REMARKS

Applicants respectfully request reconsideration of this application in view of the above amendments and the remarks below.

Pages 6, 7 and 10-11 of the specification have been amended to insert the serial numbers of the applications referred to therein.

Claims 1-20 are pending herein. Claims 1, 17, 18, and 19 are independent.

Claim 1 recites an immediate release tablet comprising at least 60 weight % of an active ingredient and a powdered wax having an melting point greater than about 90° C, said tablet meeting the USP dissolution specifications for immediate release tablets containing said active ingredient. Claim 17 recites an immediate release tablet comprising at least 60 weight percent of an active ingredient and a powdered wax selected from the group consisting of shellac wax, paraffin-type waxes, polyethylene glycol, and mixtures thereof; wherein said tablet is prepared by direct compression. Claim 18 recites an immediate release tablet comprising at least 60 weight percent of an active ingredient and a powdered wax selected from the group consisting of shellac wax, paraffin-type waxes, polyethylene glycol, and mixtures thereof; wherein said tablet is substantially free of water-soluble, non-saccharide polymeric binders. Finally, claim 19 recites an immediate release tablet comprising at least 60 weight percent of an active ingredient and a powdered wax selected from the group consisting of shellac wax, paraffin-type waxes, polyethylene glycol, and mixtures thereof; wherein said tablet is substantially free of hydrated polymers.

All of the pending claims have been rejected as obvious over U.S. Patent No. 5,494,681 to Cuca et al. alone or in combination with additional references. The Examiner argues Cuca teaches a pharmaceutical delivery system comprising an active ingredient, a wax material and a hydrophobic material. The Examiner argues that the amounts specified by applicants overlap with those disclosed by Cuca. The additional references, U.S. Patent No. 5,098,715 to McCabe et al. and U.S. Patent No. 5,681,583 to Conte, are cited to show the use of outer coatings and two active ingredients within the same dosage form respectively.

The rejections over Cuca are without merit. Cuca teaches the use of a melted wax, while the claimed invention employs powedered wax. Specifically, Cuca discloses a pharmaceutical delivery system comprising a) an active material, and b) a spatially oriented matrix. The spatially oriented matrix in turn comprises (i) a wax core material, and (ii) a regional hydrophobic polymer. Cuca's dosage form is made by melting the wax and the

hydrophobic polymer together into a liquid, and then adding the active ingredient thereto. A slurry or dispersion is thereby formed and then cooled. See column 5, line 64 to column 6, line 46. See also all of Cuca's examples.

This is in contrast to the claimed invention, in which powdered wax is employed. Each of claims 1, 17, 18 and 19 use the term "powdered."

For these reasons, applicants submit the rejections over Cuca, alone or in combination with McCabe or Conte, should be withdrawn. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: _____
Sharon E. Hayner
Reg. No. 33,058

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2242
Dated: April 3, 2003